WPC BRANDS

CORPORATE OFFICE
262-677-4121 | FAX 262 6[illegible] 901[illegible]
[illegible] REPEL ROAD • P O BOX [illegible]
JACKSON WI 53037

450304-00

January 12, 2000

Jane Mitchell
Document Processing Desk (RED-SRRD-PRB)
Office of Pesticide Programs
Room. 266A. Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington. VA 22202

VIA: Federal Express

SUBJECT: Repel 15
EPA Reg. No. 305-48
Application for Re-Registration

Dear Ms. Mitchell:

In agreement with the Reregistration Eligibility Decision (RED) for DEET, WPC Brands. is submitting an Application for Pesticide Reregistration of the subject product. Repel 15.

ENCLOSED:

The following documentation is enclosed for reregistration:

1. **Application For Pesticide-Registration:** Enclosed is a completed "Application for Pesticide" (EPA Form #8570-1) dated January 12. 2000. The application has been marked per the DEET RED as "Application for Re-registration".

2. **Product Labeling:** Enclosed are 5 copies of proposed product labeling. The proposed product labeling complies with the RED and current regulations and requirements.

3. **Confidential Statement of Formula:** Enclosed are two copies of the completed CSF's (Form #8570-4) for the basic and each alternate formulation. The CSF's are dated November 30. 1999. At the Agency's request we are claiming 98% active isomers within DEET.

4. **Formulator's Exemption Statement:** Enclosed is a completed Formulator's Exemption Statement (Form #8570-27), listing DEET as the active ingredient, which is only purchased through a registered source.

5. **Certification with Respect to Citation of Data:** Enclosed is a completed Certification with Respect to Citation of Data (EPA Form #8570-34).

6. **Data matrix:** Enclosed is the data requirement matrix listing WPC Brands, as the primary data submitter (EPA form 8570-35, both agency copy and public copy).

7. **Certification with respect to data compensation requirements:** Enclosed is the certification with respect to data compensation, (Form 8570-31).

We are submitting the following data in support of the subject re-registration

1. **Primary Skin Irritation-Volume 1: Assigned MRID No.:** 45030401
   Moore, G. E. (1999): Primary Skin Irritation Test with Repel 15 Concentrate. Unpublished study prepared Product Safety Labs, New Brunswick, NJ. 25p. Health Effects Test Guidelines. OPPTS 870.2400 (1998) (3 copies).

ACUTE TOXICITY DATA: The subject re-registration is being supported by a combination of the product-specific data being submitted with this letter and by citing data on EPA Reg. No. 305-49, which is also placed in Batch 4C/5B. The data matrix contains specific data information.

PRODUCT CHEMISTRY: Product chemistry is currently on file with the agency for the subject re-registration. We are submitting a new validated method, included within the submission for EPA Reg. No. 305-49. Due to similarity of products within batch 4C\5B, the storage study data for this product is being cited in volume 2 of Repel 29 and volume 1 of Repel 23.

The following table identifies information which is used in the support of the subject registration, that has either been previously submitted to the agency or is being cited in a different submission with in the batch.

1. **Product Chemistry:**	Assigned MRID Number: 44003801
a. Methodology	Volume 1 of EPA Reg. No.: 305-49
b. Storage study	Volume 2 of EPA Reg. No.: 305-49
c. Storage study	Volume 1 of EPA Reg. No.: 305-50
2. **Acute Oral Toxicity:**	Volume 3 of EPA Reg. No.: 305-49
3. **Acute Dermal Toxicity:**	Volume 4 of EPA Reg. No.: 305-49
4. **Acute Inhalation:**	Volume 5 of EPA Reg. No.: 305-49
5. **Primary Eye Irritation:**	Assigned MRID Number: 43956901
6. **Dermal Sensitization:**	Volume 7 of EPA Reg. No.: 305-49

Please advise if you have any additional questions or require further information.

Sincerely,

WPC BRANDS, INC.

Jean Killoren
Regulatory Coordinator
jkilloren@wpcbrands.com

Enc.

Form Approved. OMB No. 2070-0060. Approval Expires 5-31-98.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration
WPC Brands, Inc. 1 Repel Road, P. O. Box 198 Jackson, WI 53037	305-48
	Product Name Repel 15
	Date of Confidential Statement of Formula (EPA Form 8570-4) 11/30/99

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

DEET

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Active Ingredient	Source	
	Product Name	Registration Number
DEET or DEET or DEET	[redacted]	[redacted]

Signature	Name and Title	Date
Jean Killoren	Jean Killoren / Regulatory Coordinator	1/12/00

EPA Form 8570-27 (Rev. 8-95)

Product ingredient source information may be entitled to confidential treatment

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant'sName, Address, and Telephone Number WPC Brands, Inc., 1 Repel Road, Jackson WI 53037 800/558-6614	EPA Registration Number/File Symbol 305-48
Active Ingredient(s) and/or representative test compound(s) DEET	Date 12/1/99
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor Residential (Insect Repellent)	Product Name Repel 15

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature Jean Killoren	Date 1/12/00	Typed or Printed Name and Title Jean Killoren / Regulatory Coordinator

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: 1/00	EPA Reg. No./File Symbol: 305-48
Applicant's/ Registrant's Name & Address: WPC Brands, Inc. 1 Repel Road Jackson, WI	Product: Repel 15
Ingredient: DEET CAS #134-62-3	

Guideline Reference Number	Guideline Study Name	MRID Number / EPA Reg. No.	Submitter	Status	Note
Product Chemistry 158.150					
61-1	Chemical Identity	See CSF	WPC	OWN	See CSF
61-2	Begin. Mat. & Manufacture Process	440038-01	WPC	OWN	
61-3	Discussion of Formation of Impurities	440038-01	WPC	OWN	
62-1	Preliminary Analysis	NA	NA	FOR	1
62-2	Certification of Ingredients Limits	See CSF	WPC	OWN	See CSF
62-3	Analytical Method. to Verify Certified Limits	EPA Reg. 305-49 Volume 1	WPC	OWN	
63-2	Color	440038-01	WPC	OWN	
63-3	Physical State	440038-01	WPC	OWN	
63-4	Odor	440038-01	WPC	OWN	
63-5	Melting Point	NA	NA	FOR	2
63-6	Boiling Point	NA	NA	FOR	2

Signature: Jean Killoren	Name and Title: Jean Killoren / Regulatory Coordinator	Date: 1/14/00

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: 1/00	EPA Reg. No./File Symbol: 305-48
Applicant's/ Registrant's Name & Address: WPC Brands, Inc. 1 Repel Road Jackson, WI	Product: Repel 15
Ingredient: DEET CAS #134-62-3	

Guideline Reference Number	Guideline Study Name	MRID Number / EPA Reg. No.	Submitter	Status	Note
63-7	Density, Bulk Density or Spec. Gravity	440038-01	WPC	OWN	
63-8	Solubility	NA	NA	FOR	2
63-9	Vapor Pressure	NA	NA	FOR	2
63-10	Dissociation Constant	NA	NA	FOR	2
63-11	Octanol/Water Partition Coefficient	NA	NA	FOR	2
63-12	pH	NA	NA	NA	3
63-13	Stability	NA	NA	FOR	2
63-14	Oxidizing/Reducing Action	NA	NA	NA	4
63-15	Flammability	440038-01	WPC	OWN	
63-16	Explodability	NA	NA	NA	5
63-17	Storage Stability	305-49 vol. 2 305-50 vol. 1	WPC	OWN	
63-18	Viscosity	440038-01	WPC	OWN	

Signature: Jean Killoren	Name and Title: Jean Killoren / Regulatory Coordinator	Date: 1/12/00

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: 1/00	EPA Reg. No./File Symbol: 305-48
Applicant's/ Registrant's Name & Address: WPC Brands, Inc. 1 Repel Road Jackson, WI	Product: Repel 15
Ingredient: DEET CAS #134-62-3	

Guideline Reference Number	Guideline Study Name	MRID Number / EPA Reg. No.	Submitter	Status	Note
63-19	Miscibility	NA	NA	NA	7
63-20	Corrosion Characteristics	440038-01	WPC	OWN	
63-21	Dielectric Breakdown Voltage	NA	NA	NA	8
Toxicology 158.340					
81-1	Acute Oral LD_{50} - Rat	EPA Reg. 305-49 Volume 3	WPC	OWN	
81-2	Acute Dermal LD_{50} - Rat/Rabbit	EPA Reg. 305-49 Volume 4	WPC	OWN	
81-3	Acute Inhalation LC_{50} - Rat	EPA Reg. 305-49 Volume 5	WPC	OWN	
81-4	Primary Eye Irritation - Rabbit	439569-01	WPC	OWN	
81-5	Primary Dermal Irritation	EPA Reg. 305-48 Volume 1	WPC	OWN	
81-6	Dermal Sensitization	EPA Reg. 305-49 Volume 7	WPC	OWN	

1--Not produced by integrated system
2--End Use Product
3--Not dispersible in water
4--Not oxidizing or reducing
5--No explosive ingredients
6--Not required per PR 92-5
7--Not mixed w/petroleum solvents
8--Not for use around electrical equipment

Signature: Jean Killoren	Name and Title: Jean Killoren / Regulatory Coordinator	Date: 1/12/00

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: 1/00	EPA Reg. No./File Symbol: 305-48
Applicant's/ Registrant's Name & Address: WPC Brands, Inc. 1 Repel Road Jackson, WI	Product: Repel 15
Ingredient: DEET CAS #134-62-3	

Guideline Reference Number	Guideline Study Name	MRID Number / EPA Reg. No.	Submitter	Status	Note
[redacted]					
			WPC	OWN	See CSF
			WPC	OWN	
			WPC	OWN	
			NA	FOR	1
			WPC	OWN	See CSF
			WPC	OWN	
			WPC	OWN	
			WPC	OWN	
			WPC	OWN	
			NA	FOR	2
			NA	FOR	2

Signature: Jean Killoren	Name and Title: Jean Killoren / Regulatory Coordinator	Date: 1/12/00

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: 1/00	EPA Reg. No./File Symbol: 305-48
Applicant's/ Registrant's Name & Address: WPC Brands, Inc. 1 Repel Road Jackson, WI	Product: Repel 15
Ingredient: DEET CAS #134-62-3	

Guideline Reference Number	Guideline Study Name	MRID Number / EPA Reg. No.	Submitter	Status	Note
[redacted]			WPC	OWN	
			NA	FOR	2
			NA	FOR	2
			NA	FOR	2
			NA	FOR	2
			NA	NA	3
			NA	FOR	2
			NA	NA	4
			WPC	OWN	
			NA	NA	5
			WPC	OWN	
			WPC	OWN	

Signature: Jean Killoren	Name and Title: Jean Killoren / Regulatory Coordinator	Date: 1/26/00

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: 1/00	EPA Reg. No./File Symbol: 305-48
Applicant's/ Registrant's Name & Address: WPC Brands, Inc. 1 Repel Road Jackson, WI	Product: Repel 15
Ingredient: DEET CAS #134-62-3	

Guideline Reference Number	Guideline Study Name	MRID Number / EPA Reg. No.	Submitter	Status	Note
[redacted]			NA	NA	7
			WPC	OWN	
			NA	NA	8
			WPC	OWN	
			WPC	OWN	
			WPC	OWN	
			WPC	OWN	
			WPC	OWN	
			WPC	OWN	
			WPC	OWN	

Signature:	Name and Title:	Date:
Jean Killoren	Jean Killoren / Regulatory Coordinator	1/12/00

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107,
2070-057
Approval Expires
3-31-99

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name **WPC Brands, Inc.**	Company Number **305**
Product Name **Repel 15**	EPA Reg. No. **305-48**

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and amount of compensation due, if any., The companies I have notified are: (check one)

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature Jean Killoren	Date 1/22/00
Name and title (Please Type or Print) **Jean Killoren / Regulatory Coordinator**	

GENERAL OFFER TO PAY: I hearby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number: 305-48

Date of Issuance: JAN 16 1997

NOTICE OF PESTICIDE:
_X_ Registration
____ Reregistration

(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product: Repel 15

Name and Address of Registrant (include ZIP Code):

Wisconsin Pharmacal Company
1 Repel Road
Jackson, WI 53037

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

   a. Revise the EPA Registration Number to read, "EPA Reg. No. 305-48".

   b. In the Ingredients Statement, revise the total to read "100.00%".

   c. In the Statement of Practical Treatment for IF IN EYES, revise "persist" to read "persists".

Signature of Approving Official:

RPK

Richard P. Keigwin, Jr.

Date: JAN 16 1997

EPA Form 8570-6

d. Delete the following phrases from the label:

1. "for entire family"
2. "Repel 15 is designed specifically for the entire family"
3. "The soft scent is ideal for adults"

3. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Please note that the amendment to add an alternate formulation for this product (confidential statement of formula dated November 4, 1996) is also acceptable. This confidential statement of formula for an alternate formulation has been added to the product file.

A stamped copy of the label is enclosed for your records.

From
Repel 15

ACTIVE INGREDIENTS	
N,N-diethyl-m-toluamide	14.25%
Other Isomers	0.75%
INERT INGREDIENTS	85.00%
	100.0 %

CAUTION
Keep Out of Reach of Children
See back panel for additional precautions.

Net Weight oz. (gm)

Wisconsin Pharmacal Company, Inc.
Jackson, WI 53037
EPA Reg No. 305-____
EPA Est No. 3657-WI-2

ACCEPTED
with COMMENTS
In EPA Letter Dated
JAN 16 1997
Under the Federal Insecticide,
Fungicide and Rodenticide Act
as amended for the pesticide
registered under EPA Reg. No.
305-48

96 DEC -2 P2:27

RECD

Back
- Repel 15 Insect Block
- Effective, long lasting scented protection for entire family
- Effective, long lasting protection for entire family
- 15% Deet
- Hours of effective protection from mosquitoes, ticks, black flies, gnats, chiggers, no-see-ums, sand flies, deer flies, fleas and other biting insects.
- Repel 15 is designed specifically for the entire family. The soft scent is ideal for adults, the long-lasting, non-greasy formula provides exceptional effective protection.
- Non greasy and resist perspiration
- Developed especially for campers, backpackers, fisherman, hunters, golfers, bikers, hikers, joggers, ball players and active outdoors men and women

DIRECTIONS FOR USE
It is a violation of Federal Law to use this product inconsistent with its labeling.

Read all directions before using this product. DO NOT APPLY TO EYES AND MOUTH. Hold container 6 to 8 inches from skin or clothing and spray with a slow sweeping motion. Do not spray in enclosed areas. Do not spray directly on face.

To apply to face, dispense on palm of hand and spread on face and neck. Do not apply over cuts, wounds or irritated skin. Do not apply to the hands of young children. Use just enough repellent to cover exposed skin and/or clothing. Do not use under clothing. Avoid overexposure. Frequent reapplication and saturation is unnecessary for effectiveness. After returning indoors, wash treated skin with soap and water. Wash treated clothing.
Works on clothing too: Spray shirts, pants, and hats. For ticks, chiggers and fleas apply to tops of shoes and socks and around opening in outer clothing.

STORAGE: Store in a cool, dry place inaccessible to children and pets.
DISPOSAL: Do not reuse empty container. Wrap and dispose of in trash.

PRECAUTIONARY STATEMENTS:
HAZARD TO HUMANS AND DOMESTIC ANIMALS. CAUTION: Avoid contact with eyes. Harmful if swallowed. Use of this product may cause skin reactions in rare cases.

Statement of Practical Treatment: If in eyes: Flush with plenty of water. Get medical attention if irritation persist. If swallowed: Contact a physician or Poison Control Center. If you suspect that you or your child is reacting to this product, wash treated skin and call your local poison control center. If you go to a doctor, take this repellent with you.

PHYSICAL AND CHEMICAL HAZARDS: FLAMMABLE - Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° may cause bursting. Do not apply to synthetic fabrics such as acetate, rayon or spandex. Will not damage cotton, wool and nylon. May damage furniture finishes, leather, plastics, painted and varnished surfaces including watch crystals, guns, bows and automobiles.

Wisconsin Pharmacal Company

QUALITY ◇ INNOVATION

December 20, 1996

VIA: FAX (703) 305-6596 AND FEDERAL EXPRESS

Richard P. Keigwin, Jr., Product Manager 10
Document Processing Desk (APPL)
Office of Pesticide Programs - 7505C
U.S. ENVIRONMENTAL PROTECTION AGENCY
401 M Street S.W.
Washington, DC 20460-0001

Subject: Response to EPA letter dated December 13, 1996
Applications for Pesticide Registration

	EPA File Symbol
Repel 15	305-UI
Repel 29	305-UO
Repel 23	305-LN
Repel 25	305-LR
Repel 27	305-LE

Dear Mr. Keigwin,

Wisconsin Pharmacal has submitted applications to register aerosol formulations containing DEET in percentages ranging from 15% to 29%. In support of these applications, we cited certain acute toxicity data on a currently registered formula containing 35% DEET. However, for the primary eye irritation data requirement, we conducted new studies using the 15% and 29% formulas and following EPA's study protocol for aerosols. Since the results of these two studies resulted in toxicity Category IV for eye irritation, it is appropriate to assign Category IV for eye irritation to the remaining formulations, which have DEET concentrations between 15% and 29%.

EPA has questioned why these new formulas exhibit Category IV toxicity for eye irritation when the 35% formula, cited to support other acute toxicity data requirements for these products, resulted in Category II eye irritation. EPA's eye irritation protocol for aerosols calls for a 1-second burst directed at the eye from a prescribed distance. Because animals have a natural aversion to eye exposure, even from bursts of air, a short (1-second) exposure is typical of an accidental exposure from such a product. A longer exposure is difficult to imagine.

On the other hand, the amount of formulation discharged during a fixed period of release depends upon a variety of factors, including the viscosity and nature of the expelled liquid, the nature of the propellent, and the design of the valve mechanism. In the case of the DEET products under consideration, the valve mechanism is quite different from that of the currently registered 35% product, although the formulas and propellent are quite similar. This can be confirmed by examining the release rate measured and reported in the eye irritation protocol.

Formula (DEET %)	Formulation Expelled (g)	DEET Expelled (g)
35%	0.021	0.00735
29%	0.0036	0.001044
15%	0.0045	0.000675

As illustrated in the above table, a 1-second burst of the 29% formulation using its intended can-and-valve expels only one seventh the amount of DEET expelled in a 1-second burst of the 35% formula and its can-and-valve combination. Because the severity of any adverse response will depend on both the level of toxicity or irritation potential and the magnitude of the exposure, one must consider the entire aerosol product, formula, and packaging, when evaluating hazards to eyes.

For this reason, it is most appropriate for the Agency to evaluate the eye irritation potential of the new formulas using the studies conducted on the 29% and 15% formulas, since they share a basic formulation, and the same packaging, which yields lower DEET exposures. The 35% product is suitable for evaluating safety for other non-eye toxicity endpoints where the magnitude of exposure is controlled in other ways.

We have included a letter from Ed V. Buehler, Ph.D., Vice President, Scientific Affairs, Director of Toxicology for Hill Top Research, Inc. who performed all the toxicological testing for these products. Dr. Buehler's letter discusses the test variability and dosing differences (Attachment).

Primary dermal irritation and Dermal Sensitization from the studies cited for the 35% formula resulted in a Category IV classification for dermal irritation and "Non-sensitizing" for dermal sensitization. It is reasonable to assume the lower DEET formulations will not change the dermal irritation or sensitization potential of the new formulations.

With the new formulations being categorized by EPA as Category IV for eye irritation, we would not be required to have precautionary labeling statements regarding eye irritancy on the label. However, the Label Review Manual states it is acceptable for a registrant to label a Category IV product with Category III labeling, which is what we would do in the case of the eye precautionary statements.

This clarifies the difference in the eye irritation categories. Wisconsin Pharmacal wants to express our urgent desire to expedite these registrations, given previous Agency indications about these registrations, and potential commercial impact of further delay. Please let me know how we may assist the registration process.

Sincerely,

WISCONSIN PHARMACAL COMPANY, INC.

Mary Conrardy

Mary Conrardy
V. P. Lab Services

MC/dph

Attachments

December 23, 1996

Ms. Mary Conrardy
Wisconsin Pharmacal Company
1 Repel Road
Jackson, WI 53037

Dear Ms. Conrardy:

I have reviewed the eye irritation data submitted on two of your products tested on Hill Top Project Nos. 91-8128-21 A and 96-8754-21. These two products were comparable in composition, differing primarily in the concentration of active (DEET).

The product identified as REPEL FA #5-7801 contained 35% DEET (91-8128-21 A) while the product identified as IPF 29 #4 85065 contained 29% DEET. The replacement excipient was a petroleum distillate.

The original product (REPEL FA #5-7801) as tested in 1991 was slightly more irritating than the product subsequently tested in 1996 (IPF 29 #4 85065). The former product caused both opacities and iridites which are normally expected to take longer to "clear".

However, it is not apparent to me that this necessarily indicates that the two products are that much different in their irritation potential. The test system itself requires propelling the test material into the rabbit eye for a standard time and at a standard distance. Dosage then is determined by a separate weighing of the propelled test material. Because of these several variables, the actual dosage to the eye and the physical trauma of the propelled material can vary considerably from experiment to experiment. In the specific instance REPEL FA #5-7801 was estimated to be dosed at 0.021 gm and IPR 29 #4 85065 was estimated to be dosed at 0.0036 gm (5.8 fold difference).

I suspect the variables of this kind of testing are adequate to explain the differences between the two tests, and should not necessarily signify a concern that there has been some kind of change.

With highest regards, I remain,

Sincerely,

HILL TOP RESEARCH, INC.

S/Buehler

Edwin V. Buehler, Ph.D.
Vice President, Scientific Affairs
Director of Toxicology

EVB/msb

HILL TOP RESEARCH, INC.
P.O. Box 429501 • Cincinnati, Ohio 45242
513/831-3114 • Fax 513-831-1217

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA United States Environmental Protection Agency Washington, DC 20460

EXPEDITE

[X] Registration [ ] Amendment [ ] Other

OPP Identifier Number: 239223

Application for Pesticide - Section I

1. Company/Product Number: 305-UI

2. EPA Product Manager: Richard Keigwin, Jr.

3. Proposed Classification: [X] None [ ] Restricted

4. Company/Product (Name): Repel 15

PM# 10

5. Name and Address of Applicant *(Include ZIP Code)*

Wisconsin Pharmacal Company, Inc.
1 Repel Road
P.O. Box 198
Jackson, WI 53037

[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. 305-UT & 305-46

Product Name: Classic Family & Classic Sportsmen

Section - II

[ ] Amendment - Explain below.

[X] Resubmission in response to Agency letter dated Aug. 23, 1996

[ ] Notification - Explain below.

[ ] Final printed labels in response to Agency letter dated

[ ] "Me Too" Application.

[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Per agency's letter of 8-23-96 there are changes in: Name (from "Repel 15 IPF" to "Repel 15")
Data Matrix (81-1, 81-1, & 81-3)
Labeling

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[X] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
*Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [X] Label [ ] Container

4. Size(s) Retail Container: 1 oz. to 16 ounces

5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Jean Killoren	Regulatory Coordinator	1-800-558-6614

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Jean Killoren

3. Title: Regulatory Coordinator

4. Typed Name: Jean Killoren

5. Date: 9-9-96

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

EPA

United States Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Form Approved
OMB No. 2070-0060
Approval expires 9-30-90

Applicant's Name and Address	EPA File Symbol/Registration
Wisconsin Pharmacal Company, Inc. 1 Repel Road Jackson, WI 53037	305-UI
	Product Name Repel 15
	Date of Confidential Statement of Formula (EPA Form 8570-4) 9-9-96

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the following active ingredients(s):

N,N-diethyl-m-toluamide	@ 14.25%
and other isomers	@ 0.75%

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA Section 3 , and which is purchased by us from another producer.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Active Ingredient	Source	
	Product Name	Registration Number
N,N-diethyl-m-toluamide and other isomers or N,N-diethyl-m-toluamide and other isomers or N,N-diethyl-m-toluamide and other isomers	[redacted]	[redacted]

Signature	Name and Title	Date
Jean Killoren	Jean Killoren Regulatory Coordinator	9-9-96

EPA Form 8570-27 (10-86)

Product Source information May be Entitled to Confidential Treatment

EPA United States Environmental Protection Agency Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 02-28-95

Certification with Respect to Citation of Data

Applicants Name and Address

Wisconsin Pharmacal Company
1 Repel Road
Jackson, WI 53037

EPA File Symbol/Registration Number: 305-UI

Product Name: Repel 15

Date of Application: 9-9-96

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is suported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

   [ ] I am the original submitter*; or

   [ ] I have obtained the written permission of the original submitter for _____ (insert name of chemical), which is _____ (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study,

   a. [X] I am the original data submitter*; or

   [ ] I have obtained the written permission of the original data submitter for _____ (insert name of chemical), which is _____ (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*; or

   b. [ ] I have notified in writing the companies _____ (insert name of companies) for _____ (insert name of chemical) that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

   Companies _____ (insert name of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters list for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

   Companies _____ (insert name of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) that have submitted the studies which I have cited (Selective method*).

4. [X] I certify that for each study cited in suport of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature	Name and Title	Date
Jean Killoren	Jean Killoren / Regulatory Coordinator	9-9-96

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this aplication to the extent required.

Signature	Name and Title	Date

DATA REQUIREMENT LISTING

PRODUCT NAME	EPA REG. NO./FILE SYMBOL	FORMULATOR'S EXEMPTION	PAGE 1 of 3
Repel 15	305-UI	Yes	

APPLICANT'S NAME AND ADDRESS	APPLICATION FOR REGISTRATION DATED	NAME OF ACTIVE INGREDIENT
Wisconsin Pharmacal Company 1 Repel Road Jackson, WI 53037	3/12/96 original 9/9/96 resubmitted	Deet @ 14.25% Other Isomers @ 0.75%

DATA REQUIREMENTS 40 CFR REFERENCE GUIDELINE NUMBER	STUDY TITLE	SOURCE OF DATA SATISFYING REQUIREMENTS [ ] LTR [ ] OFFER COMPANY NAME	MRID/ACCESSION NO.	DATE SUBMITTED
158.150:	**PRODUCT CHEMISTRY**			
158.155:	Product composition	Wisconsin Pharmacal	MRID 44003801	3/12/96
158.160:	Description of materials used to produce the product	Wisconsin Pharmacal	MRID 44003801	3/12/96
158.162:	Description of production process	Wisconsin Pharmacal	MRID 44003801	3/12/96
158.165:	Description of formulation process	Wisconsin Pharmacal	MRID 44003801	3/12/96
158.167:	Discussion of formation of impurities	Wisconsin Pharmacal	MRID 44003801	3/12/96
158.170:	Preliminary analysis	N/A: Product is not produced by an integrated formulation system		
158.175:	Certified limits	Wisconsin Pharmacal	MRID 44003801	3/12/96
158.180:	Enforcement analytical method	Wisconsin Pharmacal	MRID 44003801	3/12/96
158.190:	**PHYSICAL AND CHEMICAL CHARACTERISTICS**			
63-2	Color	Wisconsin Pharmacal	MRID 44003801	3/12/96
63-3	Physical state	Wisconsin Pharmacal	MRID 44003801	3/12/96
63-4	Odor	Wisconsin Pharmacal	MRID 44003801	3/12/96
63-5	Melting point	N/A: End Use Product		
63-6	Boiling point	N/A: End Use Product		
63-7	Density, bulk density or specific gravity	Wisconsin Pharmacal	MRID 44003801	3/12/96
63-8	Solubility	N/A: End Use Product		

DATA REQUIREMENT LISTING

PRODUCT NAME	EPA REG. NO./FILE SYMBOL	FORMULATOR'S EXEMPTION	PAGE 2 of 3
Repel 15	305-UI	Yes	

APPLICANT'S NAME AND ADDRESS	APPLICATION FOR REGISTRATION DATED	NAME OF ACTIVE INGREDIENT
Wisconsin Pharmacal Company 1 Repel Road Jackson, WI 53037	3/12/96 original 9/9/96 resubmitted	Deet @ 14.25% Other Isomers @ 0.75%

DATA REQUIREMENTS 40 CFR REFERENCE GUIDELINE NUMBER	STUDY TITLE	SOURCE OF DATA SATISFYING REQUIREMENTS [ ] LTR [ ] OFFER COMPANY NAME	MRID/ACCESSION NO.	DATE SUBMITTED
158.190:(continued):	**PRODUCT CHEMISTRY**			
63-9	Vapor pressure	N/A: End use product		
63-10	Dissociation constant	N/A: End use product		
63-12	pH	N/A: Product is not dispersible in water		
63-13	Stability	N/A: End use product		
63-14	Oxidizing or reducing action	N/A: Product contains no oxidizing nor reducing agents		
63-15	Flammability	Wisconsin Pharmacal	MRID 44003801	3/12/96
63-16	Explodability	N/A: Product does not contain potentially explosive ingredients		
63-17	Storage stability	N/A: Not required as per EPA PR Notice 92-5		
63-18	Viscosity	Wisconsin Pharmacal	MRID 44003801	3/12/96
63-19	Miscibility	N/A: Product does not contain use directions to mix with petroleum solvents		
63-20	Corrosion characteristics	Wisconsin Pharmacal	MRID 44003801	3/12/96
63-21	Dielectric breakdown voltage	N/A: Product is not for use in/on/around electrical equipment		
158.340:	**TOXICOLOGY**			
81-1	Acute oral toxicity -- rat	EPA DEET Standard	00001085, 00001086, or 00001080	
81-2	Acute dermal toxicity	EPA DEET Standard	00001051, 05000243, or GS0002026	
81-3	Acute inhalation toxicity -- rat	EPA DEET Standard	GS0002034	

DATA REQUIREMENT LISTING

PRODUCT NAME	EPA REG. NO./FILE SYMBOL	FORMULATOR'S EXEMPTION	PAGE 3 of 3
Repel 15	305-UI	Yes	

APPLICANT'S NAME AND ADDRESS	APPLICATION FOR REGISTRATION DATED	NAME OF ACTIVE INGREDIENT
Wisconsin Pharmacal Company 1 Repel Road Jackson, WI 53037	3/12/96 original 9/9/96 resubmitted	Deet @ 14.25% Other Isomers @ 0.75%

DATA REQUIREMENTS 40 CFR REFERENCE GUIDELINE NUMBER	STUDY TITLE	SOURCE OF DATA SATISFYING REQUIREMENTS [ ] LTR [ ] OFFER COMPANY NAME	MRID/ACCESSION NO.	DATE SUBMITTED
158.340:(continued):	**TOXICOLOGY**			
81-4	Primary eye irritation -- rabbit	Wisconsin Pharmacal	MRID 43956901	3/12/96
81-5	Primary dermal irritation	Wisconsin Pharmacal	MRID 42894903	7/14/93
81-6	Dermal sensitization	Wisconsin Pharmacal	MRID 42894904	7/14/93

043

96-21-6

Wisconsin Pharmacal Company

QUALITY ◇ INNOVATION

CERTIFIED MAIL

March 12, 1996

ATTN: Richard P. Keigwin, Jr., Product Manager 10
Document Processing Desk-APPL
Office of Pesticide Programs - 7505C
U.S. ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, DC 20460-0001

SUBJECT: Repel 15 IPF
EPA File Symbol: 305-___

Dear Mr. Keigwin:

Wisconsin Pharmacal Company is submitting the enclosed materials in support of subject product's FIFRA Section 3(c(3)(b)(i) pesticide product registration. Wisconsin Pharmacal Company will act as sole agent in this endeavor.

Enclosed are the following:

VOLUME 1: ADMINISTRATIVE MATERIALS:

1. Application for Pesticide: Registration [OPP IDN 223583]
2. Five copies of proposed labeling
3. Formulation's Exemption Statement with
4. Confidential Statement of Formula (attached)
5. Certification with Respect to Citation of Data with
6. Data Requirement Listing [Matrix] (attached)
7. Safety Evaluation Summary

VOLUME 2: PRODUCT CHEMISTRY DATA: ASSIGNED MRID NUMBER: 44003801
Killoren, J. (1995): Product Chemistry Data of Repel 15 IPF. Unpublished study prepared by Wisconsin Pharmacal Company, Inc., Jackson, WI. 16p./7p. Guideline Numbers 61, 62 and 63 [3 copies].

VOLUME 3: TOXICOLOGY DATA. ASSIGNED MRID NUMBER: 43956901
Morris, Theresa, (1996): Primary Eye Irritation study in Rabbits without rinsing of Repel 15 IPF. Unpublished study prepared by Hill Top Biolabs, Inc., Miamiville, OH. 36p./3p. Guideline Number 81-4 [3 copies].

This product is substantially similar (in formulation and labeling) to Wisconsin Pharmacal's product Classic Family EPA File Symbol 305-UT and Classic Sportsmen EPA Reg. No. 305-46 and therefore qualifies for expedited review pursuant to FIFRA § 3(c)(3)(b)(i). The same percent propellent and alcohol are present in each formulation being submitted. The percent DEET declines as a low VOC/anti-irritant inert increases in the formulation (see chart).

	Application Submitted for					Previously Sub.	
	15 IPF	23 IPF	25 IPF	27 IPF	29 IPF	305-UT	305-46
DEET	15%	23%	25%	27%	29%	35%	40%
Alcohol	[redacted]						
Inert							
Propellent							
Fragrance							
Eye Irritation Tox. Cat.	III	--	--	--	III	II	II

Inert ingredient information may be entitled to confidential treatment

Repel 15 IPF has 20% less DEET than EPA file symbol 305-UT and contains an additional carrier to reduce both the total volatile organic compound (VOC) level and the Eye Irritation Toxicology category. Repel 15 IPF does not contain a fragrance.

We are submitting eye irritation data on the lowest (15%) and the highest (29%) DEET formulations and request bridging of data to the three remaining DEET formulations. Eye irritation data submitted for 15 IPF and 29 IPF are classified in FIFRA Toxicity Category III.

We are utilizing the selective method of data support to satisfy all toxicology data requirements. We are citing our own previously submitted data to satisfy the remaining acute toxicology data required. We wish to be placed on the Pesticide Data Submitter's list due to the enclosed data.

Please let me know if there is anything I may do to help expedite the registration. I may be reached at 800-558-6614.

Sincerely,

WISCONSIN PHARMACAL COMPANY, INC.

Jean Killoren
Regulatory Coordinator

Enclosures
JK/dph

29 MAR 1996

Jean Killoren
Wisconsin Pharmacal Company
1 Repel Road, P.O. Box 198
Jackson, WI 53037

Dear Ms. Killoren:

Subject: Application for Pesticide Registration
Repel 15 IPF
EPA File Symbol 305-UI
Submission Dated March 12, 1996

The application referred to above has been determined pursuant to 40 CFR 152.105 not to be sufficiently complete to process; therefore, the application is considered deficient. Labeling/other information as specified below must be submitted before the processing of the application can be completed. If such deficiencies cannot be corrected within 75 days, you must notify the Agency within those 75 days of the date you expect to complete this application. If, after 75 days you do not respond, or subsequently fail to complete the application within the time scheduled for completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by the applicant. Any subsequent submission relating to the application must be submitted as a new application.

- An administrative review of the submitted product chemistry data has identified some deficiencies. Please refer to the attached "Report of Analysis for Compliance with PR Notice 86-5" for more information.

If you have any questions or comments, please contact me at (703) 305-6788.

Sincerely yours,

RPK

Richard P. Keigwin, Jr.
Product Manager 10
Insecticide-Rodenticide Branch
Registration Division

Enclosure

N/FT

B

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States Environmental Protection Agency
Washington, DC 20460

EXPEDITE

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number: 223593

Application for Pesticide - Section I

1. Company/Product Number: 305 – UI

2. EPA Product Manager: Richard Keigwin, Jr.

3. Proposed Classification: [X] None [ ] Restricted

4. Company/Product (Name): Repel 15 IPF

PM#: 10

5. Name and Address of Applicant *(Include ZIP Code)*
Wisconsin Pharmacal Company, Inc.
1 Repel Road
P.O. Box 198
Jackson, WI 53037
[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. 305-UT and 305-46
Product Name: Classic Family & Classic Sportsmen

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[X] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: [ ] Yes* [X] No
Certification must be submitted

Unit Packaging: [ ] Yes [X] No
If "Yes" Unit Packaging wgt. / No. per container

Water Soluble Packaging: [ ] Yes [X] No
If "Yes" Package wgt / No. per container

2. Type of Container: [X] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____

3. Location of Net Contents Information: [X] Label [ ] Container

4. Size(s) Retail Container: 1 oz. up to 16 ounces

5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Jean Killoren	Regulatory Coordinator	1-800-558-6614

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: Jean Killoren

3. Title: Regulatory Coordinator

4. Typed Name: Jean Killoren

5. Date: March 12, 1996

6. Date Application Received (Stamped)

EPA

United States Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Form Approved
OMB No. 2070-0060
Approval expires 9-30-90

Applicant's Name and Address

Wisconsin Pharmacal Company, Inc.
1 Repel Road
Jackson, WI 53037

EPA File Symbol/Registration
305- III E

Product Name
Repel 15 IPF

Date of Confidential Statement of Formula (EPA Form 8570-4)
March 6, 1996

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the following active ingredients(s):

N,N-diethyl-m-toluamide	@ 14.25%
and other isomers	@ 0.75%

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA Section 3 , and which is purchased by us from another producer.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Active Ingredient	Source	
	Product Name*	Registration Number
N,N-diethyl-m-toluamide and other isomers or N,N-diethyl-m-toluamide and other isomers or N,N-diethyl-m-toluamide and other isomers	[redacted]	[redacted]

Signature	Name and Title	Date
Jean Killoren	Jean Killoren Regulatory Coordinator	3-12-96

EPA Form 8570-27 (10-86)

Product Source May be Entitled to Confidential Treatment

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 02-28-95

Certification with Respect to Citation of Data

Applicants Name and Address	EPA File Symbol/Registration Number	305- UI
Wisconsin Pharmacal Company 1 Repel Road Jackson, WI 53037	Product Name	Repel 15 IPF
	Date of Application	March 12, 1996

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is suported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

   | | I am the original submitter*; or

   | | I have obtained the written permission of the original submitter for _____ (insert name of chemical), which is _____ (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study.

   a. |X| I am the original data submitter*, or

   | | I have obtained the written permission of the original data submitter for _____ (insert name of chemical), which is _____ (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*; or

   b. | | I have notified in writing the companies _____ (insert name of companies) for _____ (insert name of chemical) that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

   Companies _____ (insert name of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters list for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

   Companies _____ (insert name of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) that have submitted the studies which I have cited (Selective method*).

4. |X| I certify that for each study cited in suport of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature	Name and Title	Date
Jean Killoren	Jean Killoren / Regulatory Coordinator	3-12-96

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this aplication to the extent required.

Signature	Name and Title	Date

DATA REQUIREMENT LISTING

PRODUCT NAME	EPA REG. NO./FILE SYMBOL	FORMULATOR'S EXEMPTION	PAGE 1 of 3
Repel 15 IPF	305-UI	Yes	

APPLICANT'S NAME AND ADDRESS	APPLICATION FOR REGISTRATION DATED	NAME OF ACTIVE INGREDIENT
Wisconsin Pharmacal Company 1 Repel Road Jackson, WI 53037	3/12/96	Deet @ 14.25% Other Isomers @ 0.75%

DATA REQUIREMENTS 40 CFR REFERENCE GUIDELINE NUMBER	STUDY TITLE	SOURCE OF DATA SATISFYING REQUIREMENTS [ ] LTR [X] OFFER COMPANY NAME	MRID/ACCESSION NO.	DATE SUBMITTED
158.150:	**PRODUCT CHEMISTRY**			
158.155:	Product composition	Wisconsin Pharmacal	Volume 2	3/12/96
158.160:	Description of materials used to produce the product	Wisconsin Pharmacal	Volume 2	3/12/96
158.162:	Description of production process	Wisconsin Pharmacal	Volume 2	3/12/96
158.165:	Description of formulation process	Wisconsin Pharmacal	Volume 2	3/12/96
158.167:	Discussion of formation of impurities	Wisconsin Pharmacal	Volume 2	3/12/96
158.170:	Preliminary analysis	N/A: Product is not produced by an integrated formulation system		
158.175:	Certified limits	Wisconsin Pharmacal	Volume 2	3/12/96
158.180:	Enforcement analytical method	Wisconsin Pharmacal	Volume 2	3/12/96
158.190:	**PHYSICAL AND CHEMICAL CHARACTERISTICS**			
63-2	Color	Wisconsin Pharmacal	Volume 2 (very faint amber)	3/12/96
63-3	Physical state	Wisconsin Pharmacal	Volume 2 (clear liquid)	3/12/96
63-4	Odor	Wisconsin Pharmacal	Volume 2 (alcohol & deet)	3/12/96
63-5	Melting point	N/A: End Use Product		
63-6	Boiling point	N/A: End Use Product		
63-7	Density, bulk density or specific gravity	Wisconsin Pharmacal	Vol 0.807 g/ml(6.73 lbs./gal)]	3/12/96
63-8	Solubility	N/A: End Use Product		

DATA REQUIREMENT LISTING

PRODUCT NAME	EPA REG. NO./FILE SYMBOL	FORMULATOR'S EXEMPTION	PAGE 2 of 3
Repel 15 IPF	305-UI	Yes	

APPLICANT'S NAME AND ADDRESS	APPLICATION FOR REGISTRATION DATED	NAME OF ACTIVE INGREDIENT
Wisconsin Pharmacal Company 1 Repel Road Jackson, WI 53037	3/12/96	Deet @ 14.25% Other Isomers @ 0.75%

DATA REQUIREMENTS 40 CFR REFERENCE GUIDELINE NUMBER	STUDY TITLE	SOURCE OF DATA SATISFYING REQUIREMENTS [ ] LTR [X] OFFER COMPANY NAME	MRID/ACCESSION NO.	DATE SUBMITTED
158.190:(continued):	**PRODUCT CHEMISTRY**			
63-9	Vapor pressure	N/A: End use product		
63-10	Dissociation constant	N/A: End use product		
63-12	pH	N/A: Product is not dispersible in water		
63-13	Stability	N/A: End use product		
63-14	Oxidizing or reducing action	N/A: Product contains no oxidizing nor reducing agents		
63-15	Flammability	Wisconsin Pharmacal	Vol. 2 Flame Extension (16")	3/12/96
63-16	Explodability	N/A: Product does not contain potentially explosive ingredients		
63-17	Storage stability	N/A: Not required as per EPA PR Notice 92-5		
63-18	Viscosity	Wisconsin Pharmacal	Volume 2 (3.6150 cst)	3/12/96
63-19	Miscibility	N/A: Product does not contain use directions to mix with petroleum solvents		
63-20	Corrosion characteristics	Wisconsin Pharmacal	Volume 2 (Not Corrosive)	3/12/96
63-21	Dielectric breakdown voltage	N/A: Product is not for use in/on/around electrical equipment		
158.340:	**TOXICOLOGY**			
81-1	Acute oral toxicity -- rat	EPA DEET Standard	MRID # 1085, 1086, 1080	
81-2	Acute dermal toxicity	EPA DEET Standard		
83-3	Acute inhalation toxicity -- rat	EPA DEET Standard	MRID # 1086	

DATA REQUIREMENT LISTING

PRODUCT NAME	EPA REG. NO./FILE SYMBOL	FORMULATOR'S EXEMPTION	PAGE 3 of 3
Repel 15 IPF	305-_____	Yes	

APPLICANT'S NAME AND ADDRESS	APPLICATION FOR REGISTRATION DATED	NAME OF ACTIVE INGREDIENT
Wisconsin Pharmacal Company 1 Repel Road Jackson. WI 53037	3/12/96	Deet @ 14.25% Other Isomers @ 0.75%

DATA REQUIREMENTS 40 CFR REFERENCE GUIDELINE NUMBER	STUDY TITLE	SOURCE OF DATA SATISFYING REQUIREMENTS [ ] LTR [X] OFFER COMPANY NAME	MRID/ACCESSION NO.	DATE SUBMITTED
158.340:(continued):	**TOXICOLOGY**			
81-4	Primary eye irritation -- rabbit	Wisconsin Pharmacal	Volume 3 (Cat III)	3/12/96
81-5	Primary dermal irritation	Wisconsin Pharmacal	MRID 42894903	7/14/93
81-6	Dermal sensitization	Wisconsin Pharmacal	MRID 42894904	7/14/93

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SAFETY EVALUATION SUMMARY

Wisconsin Pharmacal Company, Inc.
Repel 15 IPF
EPA Reg. No. 305-

STUDY TITLE	RESULTS	EPA TOX CATEGORY
Primary Eye Irritation	Corneal opacity reversible within 7 days; conjunctival irritation clearing within 7 days.	III

SIGNAL WORD: CAUTION